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No. 01-188

In The

Supreme Court of the United States

PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AMERICA,

Petitioner,

v.

KEVIN CONCANNON, Commissioner, Maine Department of Human Services, and G. STEVEN ROWE, Attorney General of Maine,

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The First Circuit

BRIEF IN OPPOSITION

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QUESTIONS PRESENTED

1. Whether the federal Medicaid statute, 42 U.S.C. § 1396 *et seq., prohibits* a state from using authority under that statute to compel drug manufacturers to provide rebates for drugs sold to uninsured Maine residents?

2. Whether the Maine Rx statute, 22 Me.Rev.Stat.Ann. § 2681 *et seq.*, which seeks rebate payments in connection with in-state retail sales of prescription drugs to uninsured Maine residents, violates the dormant Commerce Clause because wholesale transactions in those drugs occur outside of Maine?

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STATEMENT OF THE CASE

The questions presented by petitioner do not merit certiorari review. First, there is no conflict in the lower courts on the question of whether Medicaid prohibits the states from using prior authorization to induce prescription drug manufacturers to negotiate rebate agreements. Congress expressly authorized the states to impose prior authorization on any drug covered by Medicaid, without limitation. Its use in the Maine Rx program does not conflict with Medicaid, and, in fact, advances fundamental Medicaid objectives.

Second, there is no conflict on the question of whether a state law providing for such negotiated rebate agreements would infringe the dormant Commerce Clause. No other state has enacted such a law. Moreover, the well-reasoned opinion of the First Circuit is correct and carefully applies the governing analysis established by this Court's dormant Commerce Clause decisions. Petitioner's dormant Commerce Clause argument relies entirely on cases involving protectionist price-tying statutes. As the First Circuit determined, those cases are inapplicable because the Maine statute does not have the protectionist effect of a price-tying statute.

This facial challenge on a motion for a preliminary injunction is simply premature for certiorari review. The statutory system challenged here has not been implemented in Maine or anywhere else, and petitioner's theories about its possible effects on Medicaid recipients and prescription drug manufacturers require empirical evaluation that is not yet possible. Petitioner's members have not entered negotiations for rebate agreements; the Act's

prior authorization provisions have not been employed; and any impact the program might have on manufacturers remains entirely speculative.

I. The Maine Rx Program

Maine residents without prescription drug insurance coverage often cannot afford to purchase the medicines their doctors prescribe. Maine Rx is a new program designed to give these consumers the benefit of a price discount similar to that enjoyed by consumers covered by private and governmental health plans, which are able to make bulk purchases of drugs. Pharmacies will offer this discount on those drugs that are manufactured by pharmaceutical companies that have elected to participate in the program. Maine will reimburse the pharmacies for giving the discount, and it will pay the pharmacist a modest dispensing fee. 22 Me.Rev.Stat.Ann. § 2681(6)(D), reproduced in the appendix to the petition for a writ of certiorari at 89 (hereinafter "*Pet. App.*"). Maine will fund the program, on a continuing basis, by collecting a rebate payment for each prescription filled from the participating manufacturer. 22 Me.Rev.Stat.Ann. § 2681. *Pet. App.* at 86.

The Commissioner of the Maine Department of Human Services (the "Commissioner" and the "Department") and each manufacturer that elects to participate in the program will enter into negotiations to determine the size of the rebate to be paid, and thus the size of the discount to be offered, for that manufacturer's drugs. 22 Me.Rev.Stat.Ann. § 2681(4). *Pet. App.* at 87. The Act directs the Commissioner to use his "best efforts" to

negotiate Maine Rx rebates that are as generous as those which manufacturers provide when the state purchases their drugs on behalf of Maine's Medicaid recipients. 22 Me.Rev.Stat.Ann. § 2681(4)(B). *Pet. App.* at 88. The Act does not, however, require that this or any other rebate amount be achieved in the rebate negotiations.

A participating manufacturer's assumed obligation to pay a Maine Rx rebate is triggered by the retail sale in Maine of the participating manufacturer's drug to a Maine resident by a Maine pharmacy. The obligation does not depend on where the manufacturer is located or where wholesale transactions involving the manufacturer's products take place. Moreover, the Act does not dictate what manufacturers may charge for their products, and manufacturers may change their prices without any consequences whatsoever. The program only seeks to obtain a rebate, the amount of which is fixed by negotiation (though revisited each year).

Participation in the program is voluntary and twenty-seven non-PhRMA members had agreed to participate before the district court ruled on PhRMA's preliminary injunction motion. *JA* at 144.[1] To be sure, a manufacturer's election not to participate carries certain potential consequences. Chief among these consequences is the mechanism Maine Rx employs to encourage participation. Specifically, the Act instructs the Department to "impose prior authorization requirements in the Medicaid program . . . *as permitted by law*, for the dispensing of

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[1] Citations with the notation "JA" refer to items in the parties' Joint Appendix before the court of appeals.

prescription drugs provided by those manufacturers" that elect not to participate in the Maine Rx program. 22 Me.Rev.Stat.Ann. § 2681(7) (emphasis added). *Pet. App.* at 89-90.

"Prior authorization" is a device found in many public and private health plans and is simply a requirement that the permission of the plan's administrator be obtained by a physician before reimbursement will be allowed for the dispensing of particular drugs. This device, which is an expression of a health plan's purchasing preference for certain drugs, is premised on the economic reality that competing companies market comparable drugs that are often equally effective in treating a given medical disorder. A health plan administrator will typically approve a physician's request to dispense a drug appearing on the plan's prior authorization list upon demonstration that it is in the patient's best interest to do so. Under Maine Rx, the possibility that a drug will be subjected to prior authorization provides an incentive for manufacturers to participate in the program because imposition of a prior authorization requirement may be detrimental to the manufacturer's market share of that drug when adequate therapeutic alternatives exist.

Federal Medicaid law gives broad authority to the states "to subject to prior authorization *any* outpatient drug." 42 U.S.C. § 1396r-8(d)(1)(A) (emphasis added). *Pet. App.* at 78. Medicaid does not dictate, or in any way limit, how a state goes about identifying the specific drugs for

which it will require prior authorization.[2] It also does not mandate criteria to be used in reviewing individual physician requests to prescribe a drug appearing on the prior authorization list.

II. District Court Proceedings

PhMRA filed its complaint and motion for a preliminary injunction on August 10, 2000, one day before the Act's effective date and over four months before the program was to begin. The parties briefed the legal issues raised by the motion without taking discovery, and filed only a few affidavits and a handful of supporting materials with the briefs. In short, this case came up for review as a purely facial challenge to a unique program, with no record of the actual effect the Act may have on manufacturers, Medicaid recipients or eligible consumers.

In its analysis of the preliminary injunction request, the district court construed the Maine Rx program as a price control measure. It determined that although the Act does not discriminate against commerce of other

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[2] As the court of appeals found, the Department has itself proposed administrative rules governing prior authorization under Maine Rx and "aimed at ensuring that Medicaid recipients will have access to needed medications." *Pet. App.* at 12. As the court noted, "the decision to place a drug on the prior authorization list may be made only by the State's Medicaid Drug Utilization Review [DUR] Committee, which exclusively comprises physicians and pharmacists licensed to prescribe or dispense medications in Maine." *Id.*

states, Maine lacks authority over out-of-state manufacturers under this Court's dormant Commerce Clause cases. *Pet. App.* at 64-65. On the Supremacy Clause issue, the district court determined that the Act fails to advance any Medicaid purpose, and that its use of prior authorization – although expressly authorized by Congress – was nonetheless an obstacle to Congress' objectives in enacting Medicaid. *Pet. App.* at 68. The district court granted the preliminary injunction on October 26, 2000.

The Maine Rx program has been in limbo since that date. Although several companies have signed rebate agreements, no PhRMA member company has even entered into negotiations. No company has yet paid a rebate, and no drug has been subjected to prior authorization under the Act. Of course, eligible consumers have not yet received any Maine Rx discounts.

III. Decision of the First Circuit

A unanimous panel of the First Circuit[3] reversed the district court and vacated the temporary injunction. *Pet. App.* at 29. As the district court did, the court of appeals focused its attention on the "likelihood of success" prong of the preliminary injunction calculus. Before reaching the principal issues, however, the court of appeals determined that PhRMA has prudential standing to lodge its

[3] Although petitioner did not object prior to the ruling, it now notes that the panel contained no active judge of the First Circuit. *Pet.* at 6. All three judges on the panel are federal judges – two district court judges and one senior circuit judge. The composition of the panel was proper pursuant to 28 U.S.C. § 46(b), and PhRMA cannot suggest otherwise.

Supremacy Clause challenge, and that it may invoke the rights of Medicaid recipients it claims are disadvantaged by the Act. *Pet. App.* at 7-8. Turning to PhRMA's preemption argument, the court of appeals observed that Congress expressly authorized the states to impose prior authorization on any prescription drug covered by a state Medicaid program. The court noted that the only limits on that express grant of power are requirements that the state respond quickly when a patient presents a prescription subject to prior authorization, and that a 72-hour supply be provided in emergencies. *Pet. App.* at 11. PhRMA does not contend that the Act fails to meet these requirements.

The court of appeals then rejected PhRMA's argument that the Maine Rx program must be preempted by Medicaid because it fails to advance any "Medicaid purpose." *Pet. App.* at 12. First, the court determined that the mere failure to advance a federal program is not the proper test for applying the "strong medicine" of preemption. *Pet. App.* at 13. Second, the court found that the Maine Rx program does, in fact, advance the goals of Medicaid by keeping people healthy and preventing them from falling into poverty and dependence on Medicaid and other programs. *Pet. App.* at 13-14. The First Circuit "perceive[d] no conflict between the Maine Act and Medicaid's structure and purpose," the proper analysis of PhRMA's implied conflict preemption claim. *Pet. App.* at 11.

The court of appeals also rejected PhRMA's claim that the Maine Rx program would interfere with the best interests of Medicaid recipients, finding that "at this point in the proceedings, [there is an] insufficient basis

for concluding that the Maine Act, on its face, controverts" such interests. *Pet. App.* at 15. In particular, the court found that "there is no evidence that the prior authorization procedure is likely to foreclose a patient from receiving a necessary drug." *Pet. App.* at 16. Recognizing that the picture may change as the Act is implemented, the court noted that PhRMA could readily renew its challenge if actual experience with the program showed some tangible interference with the objectives of Medicaid. *Pet. App.* at 17.

The First Circuit went on to dispose of PhRMA's contention that the Maine Rx rebate provisions infringe the dormant Commerce Clause. The court of appeals applied a three-step analysis to the dormant Commerce Clause claim. First, it determined that the statute was not subject to a *per se* analysis because it does not have an "extraterritorial reach." *Pet. App.* at 20-24. It next determined that strict scrutiny did not apply because the statute was not enacted for a discriminatory purpose and does not have a discriminatory effect. *Pet. App.* at 24-25. Finally, the court of appeals determined that the Act regulates evenhandedly and any effect it may have on interstate commerce is merely incidental. *Pet. App.* at 25. Applying the balancing test articulated by this Court in *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970), the court of appeals determined that the impact on manufacturers is both speculative and not the kind of effect the dormant Commerce Clause is meant to preclude. *Pet. App.* at 26-27. Accordingly, the court of appeals reversed the district court decision in its entirety and vacated the preliminary injunction. *Pet. App.* at 29.

The First Circuit denied petitioner's request for a panel rehearing and for a rehearing *en banc* but temporarily stayed its mandate pending PhRMA's petition for a writ of certiorari. *Pet. App.* at 54-55.

REASONS FOR DENYING THE WRIT

I.

There Is No Compelling Reason To Review the Decision of the Court of Appeals.

The questions presented by the First Circuit's decision do not warrant certiorari review by the Court. As a preliminary matter, however, it is necessary to correct the framing of the questions presented in the petition.

Under this Court's jurisprudence in the area of "conflict preemption" under the Supremacy Clause, a state's exercise of its sovereign powers in enacting legislation is legitimate unless constitutionally permissible federal legislation on the subject clearly prohibits the state effort, either expressly or by implication. *Gade v. National Solid Waste Management Association*, 505 U.S. 88 (1992). The question which PhRMA's preemption challenge to the Act presents is therefore not whether the Medicaid statute *allows* use of prior authorization in the manner contemplated by Maine Rx. *Pet.* at i. Rather, the proper constitutional test, and question presented, is: Whether the federal Medicaid statute *prohibits* a state from using

authority under that statute to compel drug manufacturers to provide rebates for drugs sold to uninsured Maine residents?[4]

Likewise, petitioner frames the dormant Commerce Clause question around the unwarranted assumption that the rebate provision is either a "tax" or a "regulation." *Pet. App.* at i. Maine, however, is not using its taxing or regulatory power. The State is only using its purchasing power in Medicaid to induce manufacturers to discount their products when purchased by Maine residents without insurance. The negotiated agreements establishing those discounts are not a tax or a regulation of interstate commerce. Yet, by using these terms to mischaracterize the Maine Rx program, PhRMA proposes a question that is improperly argumentative. SUP. CT. R. 14.1.(a) The question raised by PhRMA's dormant Commerce Clause challenge, rather, is: Whether Maine Rx, 22 Me.Rev.Stat.Ann. § 2681 *et seq.*, which seeks rebate payments in connection with in-state retail sales of prescription drugs to uninsured Maine residents, violates the dormant Commerce Clause because wholesale transactions in those drugs occur outside of Maine?

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[4] Indeed, petitioner's assertion of a conflict between the First Circuit's decision here and a recent decision of the District of Columbia Circuit is internally consistent only because of the use of the wrong verb ("allows") in PhRMA's proposed question presented. As is demonstrated at pages 11-12 below, the claim of a conflict does not survive even a cursory reading of the two court of appeals opinions.

A. There is No Compelling Reason to Review the Supremacy Clause Ruling.

1. The First Circuit Decision Does Not Conflict With the Decision of Other Federal Circuit Courts.

As the parties and the court of appeals agreed, this is a Supremacy Clause case of the "implied conflict preemption" variety. *Pet. App.* at 9. Thus far, no statute bearing material similarities to Maine Rx or raising the same Supremacy Clause concerns has been the subject of litigation outside of the First Circuit. There is therefore no disarray in the law or lower court development of jurisprudence on this issue requiring this Court's attention now.

The only case that petitioner suggests is in conflict with the present one, *PhRMA v. Thompson*, 251 F.3d 219 (D.C. Cir. 2001), raises no Supremacy Clause question. It is only a statutory construction case. The issue before the District of Columbia Circuit was whether the federal Department of Health and Human Services exceeded its statutory authority when it approved an experimental "demonstration" project for Vermont's Medicaid program. *Id.* at 222-23. Resolution of this issue turned exclusively on the question of what the term "payment" means in the provision of the Medicaid statute which requires that participating manufacturers provide rebates on drugs for which "payment was made under the state plan." *Id.* at 223-26.

Although even a cursory reading of the two opinions reveals that no conflict is present, PhRMA desperately seeks to conjure up one. It voices the superficial, and

imprecise, observation that the demonstration project at issue in *Thompson* and the Maine Rx program each employ the "leverage of Medicaid." *Pet.* at 13. But two appellate decisions, addressing different legal questions raised by two different programs, do not create a conflict of the sort to be resolved on certiorari review simply because one program is struck down while the other is upheld or because they each implicate different aspects of Medicaid.

2. The Court of Appeals' Resolution of the Supremacy Clause Question is Consistent With this Court's Precedents.

Not only did the First Circuit answer a question that is different from both the question answered in *Thompson* and the "question presented" which PhRMA now offers, but the lower court answered it in a manner consistent with bedrock principles of constitutional law as explained by this Court. First and foremost among those principles is the assumption "that the historic police powers of the States [are] not to be superceded by the Federal Act unless that [is] the clear and manifest purpose of Congress," *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947), or, in the words of the First Circuit, preemption is "strong medicine . . . not casually to be dispensed." *Pet. App.* at 10.

Following strictly the approach mandated by *Gade v. National Solid Waste Management Association*, 505 U.S. 88 (1992), the court of appeals conducted an exhaustive examination of the language, structure, and "discernable objectives" of the federal Medicaid statute. *Pet. App.* at

10-17. This search uncovered nothing suggesting that Congress intended to prohibit the use of a state's broad prior authorization discretion to accomplish a goal shared by both Medicaid and Maine Rx – promoting the health of Maine's people by making prescription medicine readily available to citizens whose "income and resources are insufficient to meet the costs of necessary medical services." 42 U.S.C. § 1396; *Pet. App.* at 13. *See also* 22 Me.Rev.Stat.Ann. § 2681(1) (Maine Rx program goals); *Pet. App.* at 86.

The First Circuit also reviewed the scant record developed on the motion for preliminary injunctive relief and found that PhRMA had failed to establish, as is required in order for its facial challenge to succeed, that implementation of Maine Rx "will inflict inevitable or even probable harm on Medicaid patients or their providers." *Pet. App.* at 16. While this finding is indeed contrary to that of the district court, the conclusions which may be drawn from the affidavits submitted by the parties is not an issue meriting review by this Court. *See* R. Stern, E. Gressman, S. Shapiro & K. Geller, *Supreme Court Practice*, § 4.17 (7th ed. 1993).

3. Substantial Questions Exist As to Whether PhRMA Has Standing to Bring a Supremacy Clause Challenge to Maine Rx.

Another problem with this petition is that PhRMA, a pharmaceutical industry trade association, may not have prudential standing under this Court's "zone of interests" test to bring a claim that Maine Rx is preempted by Medicaid. Standing appears to be wanting because

PhRMA does not seek to vindicate an interest it holds which is even arguably within the zone of interests protected or regulated by the allegedly preemptive Medicaid statute. *National Credit Union Administration v. First National Bank & Trust Co.*, 522 U.S. 479, 492 (1998). PhRMA's interest here is merely a desire to protect the market share of its members' products from the effect of prior authorization. Medicaid does not protect this interest and PhRMA does not argue otherwise.[5]

The First Circuit did not look, however, to the interests protected by Medicaid to find that PhRMA satisfies the prudential standing requirement. Instead, the court held that the zone of interests test is satisfied because PhRMA's interests are protected by the Supremacy Clause itself. *Pet. App.* at 7. This was error because, unlike other provisions of the constitution, the Supremacy Clause cannot itself provide the sort of interest which satisfies the zone of interests test for the simple reason that the Supremacy Clause does not, by its own force, create any federal rights. As explained by the Court in *Golden State Transit v. City of Los Angeles*, 493 U.S. 103, 107 (1989), a party may not bring an action under 42 U.S.C.

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[5] The requirement that Medicaid funds be expended only on those drugs for which manufacturers have agreed to sell at a discount (a discount collected through a rebate payment), is not, as PhRMA suggested below, a form of regulation of the pharmaceutical industry. 42 U.S.C. § 1396r-8(a)(1). *Pet. App.* at 73. Nothing in federal law *requires* a manufacturer to provide a Medicaid rebate in the first instance. Manufacturers do so only after electing to take advantage of the sizable market for their products created by Medicaid. Offering a discount in order to gain entry into this market can hardly be viewed as a form of "regulation" of the drug industry.

§ 1983 for violation of the Supremacy Clause for the fundamental reason that the Supremacy Clause does not itself confer federal rights. *See also Dennis v. Higgins*, 498 U.S. 439, 449 (1991) (noting that the question of whether a particular constitutional provision confers a federal right enforceable under § 1983 is related to the question of whether that constitutional provision protects an interest sufficient to satisfy the zone of interests test). In fact, if the Supremacy Clause alone could provide the basis for prudential standing, as the court of appeals held, then any person seeking to bring a Supremacy Clause challenge to a state statute would have prudential standing no matter how far removed that person is from the interests protected or regulated by the allegedly preemptive federal statute. Yet, the decision below on the standing issue diminishes the zone of interests test in precisely this fashion.

PhRMA's standing to raise vicariously the claim of a Medicaid recipient, that Maine Rx infringes his or her interest in obtaining drugs free from prior authorization requirements, is further suspect because it is questionable whether a Medicaid recipient could, in fact, bring such a claim. *See Westside Mothers v. Haveman*, 133 F.Supp.2d 549 (E.D. Mich. 2001) (Medicaid recipients may not bring an action against state officials to enforce Medicaid's requirements because Medicaid was enacted pursuant to Congress' "spending power" under Article I, section 8, of the Constitution and thus its requirements are not the "supreme Law of the Land."). This issue of federalism, and the prudential standing issue to which it is related, would have to be addressed by this Court if it were to

accept this case for review. These issues were not, however, the object of significant attention by the First Circuit. Their presence here, however, makes this case a poor vehicle for review in this Court of the constitutional issues PhRMA seeks to raise.

B. There Is No Compelling Reason To Review the Dormant Commerce Clause Ruling.

1. The First Circuit Decision Does Not Conflict With the Decisions of Other Federal Circuit Courts.

The First Circuit's decision upholding Maine Rx against PhRMA's dormant Commerce Clause challenge does not conflict with the decision of any other Circuit. Indeed, petitioner does not allege such a conflict. Certiorari review of the dormant Commerce Clause question is therefore not warranted [6]

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[6] Petitioner cites several lower court cases without claiming that they represent a conflict in the circuits. *See Pet.* at 14, citing *Dean Foods Co. v. Brancel*, 187 F.3d 609 (7th Cir. 1999) (invalidating Wisconsin milk volume discount statute as applied to transactions taking place at Illinois milk processor); *Louisiana Dairy Stabilization Bd. v. Dairy Fresh Corp.*, 631 F.2d 67 (5th Cir. 1980) (invalidating milk processing regulation that required payment of fees to protect Louisiana dairy industry); *Schwegmann Bros. Giant Super Mkts. v. Louisiana Milk Comm'n*, 365 F.Supp. 1144 (M.D. La. 1973), *aff'd mem.* 416 U.S. 922 (1974) (invalidating Louisiana minimum price regulation as applied to wholesale transaction in Tennessee). *Dean Foods* and *Schwegmann* involved price control statutes that directly constrained the price in transactions taking place outside the state's borders. *Louisiana Dairy Stabalization Bd.* involved a fee system that was applied to out-of-state transactions in order to protect in-state milk producers. None of these cases conflicts with the First Circuit's decision because the Maine Rx negotiated rebates agreements simply do not control prices extraterritorially and do not protect in-state industries.

2. Petitioner's Argument that the Maine Rx Program Is A Tax Was Not Part of the Court of Appeals' Decision Under Review.

Petitioner contends that the negotiated rebates are actually a tax and should be enjoined under *Complete Auto Transit, Inc. v. Brady*, 430 U.S. 274 (1977). *Pet.* at 19-21. This Court need not review that argument because it was not part of the decision below. *Pet. App.* at 27, n.11. Moreover, the question of whether the manufacturers have a substantial nexus with Maine, as is required of a tax under *Complete Auto*, would be a heavily fact-bound inquiry into the extent to which retail sales through the Maine Rx program would be attributed to the employees, advertising and other activities of the manufacturers within Maine. *Complete Auto* at 277-78. There is no record evidence on that question. In any event, if the Maine Rx rebate *is* a "tax," petitioner has brought its case in the wrong forum. The federal district court does not have jurisdiction to enjoin a state tax. Tax Injunction Act, 28 U.S.C. § 1341.

3. The First Circuit's Decision Is Consistent With the *Baldwin/Brown-Forman/Healy* Decisions.

The court of appeals correctly determined that this Court's extraterritorial price control cases – *Healy v. The Beer Institute*, 491 U.S. 324 (1989), *Brown-Forman Distillers*

Corp. v. New York State Liquor Auth., 476 U.S. 573 (1986), and *Baldwin v. G.A.F. Seelig*, 294 U.S. 511 (1935) – do not support petitioner's dormant Commerce Clause claim. *Pet. App.* at 20-24.[7] Each of these cases involved state statutes that had the practical effect of directly regulating extraterritorial prices, locking the in-state price to those charged in another state. Tying prices in one state to those in another was incompatible with the Commerce Clause because it warped the interstate marketplace.

The Maine Rx statute does not have that effect, either directly or indirectly. Simply put, it does not tie in-state prices to pricing elsewhere. It does not constrain manufacturers' pricing freedom, and does not interfere with economic forces. The Maine Rx system is a program of quarterly rebate payments determined by the volume of in-state retail sales multiplied by a rebate amount that is separately negotiated with each manufacturer. It does not include a wholesale price control mechanism, either directly or indirectly, and does not have that "practical effect." *Healy*, 491 U.S. at 337.[8] Maine simply has not

[7] The Court of Appeals correctly applied the analysis of *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970), finding that the Act "regulate[s] evenhandedly" and any "incidental effects on interstate commerce" are "clearly outweigh[ed by] the putative local benefits." *Pet. App.* at 25-27.

[8] The "critical consideration" in dormant Commerce Clause review is "the overall effect of the statute on both local and interstate activity." *Brown-Forman*, 476 U.S. at 579. Unlike the price-tying cases, the practical effect of the Maine Rx statute is not obvious in this facial challenge.

"prescribe[d] the rule by which commerce is to be governed." *Gibbons v. Ogden*, 22 U.S. 1 (9 Wheat.) (1824). This fundamental structural difference renders *Baldwin*, *Brown-Forman* and *Healy* inapposite.[9]

Equally significant, the rationale underlying *Baldwin*, *Brown-Forman* and *Healy* does not apply here. Each of those cases relied on the core dormant Commerce Clause value of an open competitive market, free from the discriminatory legislation of the several states. Petitioner, however, does not even allege that the Act has any such anti-competitive or discriminatory effect. As the Court noted in *Brown-Forman*, "a State may seek lower prices for its consumers, [so long as it does] not insist that producers or consumers in other States surrender whatever competitive advantages they may possess." 476 U.S. at 580. That is precisely what Maine has done.

Petitioner invites the Court to expand the dormant Commerce Clause far beyond its essential purpose of ensuring that the interstate market is unencumbered by

[9] Those cases are inapposite for an additional reason. In each case the state sought to sanction non-compliant businesses, whereas the only consequence to manufacturers who do not enter Maine Rx rebate negotiations is that their sales to the Maine Medicaid program may decline somewhat. Maine, therefore, is using its power as a market participant, not its regulatory authority, and the dormant Commerce Clause is not implicated. *See White v. Massachusetts Council of Construction Employers, Inc.*, 460 U.S. 204 (1983); *Reeves, Inc. v. Stake*, 447 U.S. 429 (1980); *Hughes v. Alexandria Scrap Corp.*, 426 U.S. 794 (1976). The Court of Appeals rejected respondents' market participation argument. *Pet. App.* at 20.

discriminatory state legislation.[10] *See CTS Corp. v. Dynamics Corp. of America*, 481 U.S. 69, 87 (1987) ("[t]he principal objects of dormant Commerce Clause scrutiny are statutes that discriminate against interstate commerce"); Donald Regan, *The Supreme Court and Economic Protectionism: Making Sense of the Dormant Commerce Clause*, 84 Mich. L. Rev. 1091, 1092 (1986) (in dormant Commerce Clause cases "the Court has been concerned exclusively with preventing states from engaging in purposeful economic protectionism"). Only discriminatory statutes or those that control the terms of trade in other states have been invalidated on a *per se* basis. *Brown-Forman*, 476 U.S. at 578-79.[11] The dormant Commerce Clause has never been a categorical ban on state statutes with incidental extraterritorial effects. *See CTS Corp. v. Dynamics Corp. of America*, 481 U.S. 69 (1987) (upholding state anti-takeover law that applied to extraterritorial transactions); *Exxon Corp. v. Governor of Maryland*, 437 U.S. 117, 126-28, *reh. denied sub nom., Shell Oil Co. v. Governor of Maryland*, 439 U.S. 884 (1978) ("The fact that the burden of a state regulation falls on some interstate

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[10] PhRMA raises the specter of states taxing oil from Texas or computer chips from California. *Pet.* at 17 n.6 Such blatantly discriminatory legislation is a far cry from the non-discriminatory negotiated rebate agreements at issue here.

[11] Indeed, in the "price-tying" section of its petition PhRMA acknowledges that the dormant Commerce Clause cases apply the *per se* rule only when a statute requires a manufacturer to "factor the in-state price ramifications into their pricing calculations," which the Act does not. *Pet.* at 18-19. As explained below, although that section of the petition correctly depicts the dormant Commerce Clause, it fundamentally misrepresents the Act.

companies does not, by itself, establish a claim of discrimination against interstate commerce. . . . The Commerce Clause protects the interstate market, not the particular interstate firms, from prohibitive or burdensome regulations"). The dormant Commerce Clause simply does not prohibit state laws that affect the profitability of out-of-state entities whose products are consumed within the State.[12]

Petitioner relies heavily on its mischaracterization of the actual language of the Act. Petitioner contends that the Act "specifies that the rebate required of manufacturers shall equal or exceed the rebates required around the country under Medicaid and other federal programs. 22 Me.Rev.Stat.Ann. § 2681(3), (4)." *Pet.* at 18. The actual language of the cited provisions, however, belies petitioner's assertion, in two ways. First, § 2681(4) provides that the amount of the rebates is to be *negotiated* between the Commissioner and each separate manufacturer. No minimum rebate is "specified." As Judge Keeton's

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[12] Petitioner asserts that drug manufacturers' profits constitute "ancillary terms" of the wholesale transaction, *Pet.* at 17, and that therefore any state regulation that reduces profits is a forbidden regulation of interstate commerce. But "profit" is a concept related to the overall operations of an entire company; it is not a "term" of the sale transaction between the manufacturer and its customer. The distinction is fundamental. Regulating the terms of wholesale transactions would interfere with the laws of supply and demand that the dormant Commerce Clause evolved to protect. But countless state laws and regulations affect retail transactions in ways that reduce the profits of companies located elsewhere, and no one suggests that such laws automatically violate the Commerce Clause.

concurring opinion emphasized, the rebate provision "is *not* a statutory mandate." *Pet. App.* at 42. (emphasis in original). Petitioner's disagreement with the court of appeals' interpretation of a state statute is of little national interest and does not warrant this Court's review.

Equally important for dormant Commerce Clause purposes is that, while the Commissioner is directed to use his "best efforts" to negotiate rebates approaching those offered through other public assistance programs, the Act simply does not tie the rebates to those amounts or to any other index. Manufacturers may negotiate rebate agreements unrelated to any other price, leaving them free to change prices anywhere without regard to the Maine Rx rebate agreement.[13] Unlike *Baldwin*, *Brown-Forman* and *Healy*, Maine simply has not "establish[ed] a . . . scale of prices for use in other states," directly or indirectly. *Baldwin*, 294 U.S. at 528.

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[13] The Maine legislature understood that there would be real negotiations between the Commission and the manufacturers, and that there was no guarantee that manufacturers would agree to substantial rebates. For example, if the legislature believed it had enacted mandatory rebates, as PhRMA alleges, the separate price control provisions would have been superfluous. *See* 22 Me.Rev.Stat.Ann. § 2693(1)(B). *Pet. App.* at 96. Those retail price controls take effect on July 1, 2003, but only if the rebates negotiated by the Commissioner are insufficient. *Id.* The negotiation process was halted by this lawsuit, and the size of the rebates manufacturers would have agreed to had the process continued remains a matter of speculation.

II.

The Context In Which the Issues Are Framed in this Case Make it an Inappropriate Vehicle for Certiorari Review

Petitioner prematurely seeks certiorari review of its facial challenge to Maine Rx at the preliminary injunction stage. The court of appeals, however, recognized that the present posture of this case, together with the particular brands of constitutional arguments PhRMA asserts, makes it difficult to assess what impact, if any, Maine Rx will have on Medicaid patients and on interstate commerce. As the court noted, "[b]ecause this is a facial challenge to a statute, PhRMA has a difficult burden of showing that Medicaid recipients will be harmed by the Maine Rx Program." *Pet. App.* at 15. The court further recognized that the affidavits submitted in connection with the preliminary injunction motion, "along with other materials in the record, fall short of establishing that the Act will inflict inevitable or even probable harm on Medicaid patients." *Id.* at 16. Agreeing that a more robust factual record would permit review of PhRMA's claims without the need for prediction or speculation, the court specifically provided that its "decision is without prejudice to PhRMA's right to renew its preemption challenge after implementation of the Act, should there be evidence that Medicaid recipients are harmed by the prior authorization requirement "as applied." *Id.*[14]

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[14] Respondents take issue with PhRMA's suggestion that to wait for an "as applied" challenge would be to conduct outrageous "human experimentation" on patients. *Pet.* at 10. Certainly PhRMA's drug manufacturer members cannot dispute

The possible scope of a future "as applied" review of PhRMA's Commerce Clause challenge was also noted by the court. For instance, the Commissioner's negotiations with manufacturers for rebate agreements may, in practice, "become coercive or otherwise inappropriate" so as to create "an issue that needs to be revisited once the Act takes effect." *Pet. App.* at 23. Similarly, the balancing required by *Pike*, 397 U.S. at 142, of the local benefits of Maine Rx against any burden it might place on interstate commerce, can be more concrete and searching once the statute has been implemented. Thus, although the court held that, "[f]or now, it is enough to say that the Act survives the facial challenge under the dormant Commerce Clause," it welcomed a future, as applied challenge. *Pet. App.* at 27. The court described the problems posed by deciding this case in its present posture: "[i]t is necessary to recognize the difficulty in foreseeing what events actually will occur from the enforcement of this Act, which admittedly makes the *Pike* balancing test more challenging to apply. We are forced to balance the *possible* effects, instead of the *actual* effects of the statute in action." *Id.* The same considerations concerning the present posture of this facial challenge to Maine Rx that informed the approach of the court of appeals undermine this petition.

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that making life-saving prescription drugs more available to those least able to afford them – the goal of Maine Rx – will promote rather than jeopardize the health of Maine's citizens. It is also beyond dispute that whichever medicine Medicaid recipients receive, it will already have been proven safe and efficacious through appropriate clinical trials.

III.

Petitioner's Characterization of the Need For Immediate Review by this Court Is Overstated.

Maine is the only state to have enacted a statute which uses the Medicaid prior authorization discretion to encourage manufacturer rebates to help lower prescription drug prices for the uninsured. And, it is also the only state to use manufacturer rebates to fund an entirely state-run public benefits program. While Maine's legislation may well have sparked a healthy debate regarding prescription drug programs in other states, PhRMA mischaracterizes the imminence of the revolution it fears.

The handful of state proposals mentioned by PhRMA is hardly a groundswell. For example, the Alabama bill discussed at length by petitioner had already failed by the time PhRMA filed its petition. *See National Conference of State Legislatures, 2001 Prescription Drug Discount, Bulk Purchasing, and Price-related Legislation*, at http://www.ncsl.org/programs/health/drugdisc01.htm (updated August 20, 2001). Proposals in other states mentioned in the petition had either failed to win enactment (Arkansas; Minnesota; Oregon) or had been replaced by legislation lacking the prior authorization mechanism at issue here (Louisiana). *Id., see also* H.B. 2057, 2001 Reg. Sess. (La. 2001) (substituted for H.B. 1089). As one of petitioner's spokespersons, an assistant general counsel to PhRMA, recently said, "I'm not sure that Maine is heading a parade because I'm not sure there is a parade behind them." Francis X. Quinn, *Maine leads quest for cheaper drugs, but is anyone following?*, Associated Press

(AP) Newswires, August 11, 2001, at 1. *See also* Francis X. Quinn, *Maine in lead in drug-cost policy / But example may be too hard to follow for many other states*, Houston Chronicle, August 12, 2001, 2001 WL 23620764, at 1-2.

In addition, the particular constitutional problems alleged in PhRMA's challenge to Maine Rx – federal preemption and the dormant Commerce Clause – are both capable of being and may be resolved by Congress. Federal drug price regulation, pursuant to Congress' Commerce Clause powers, could be made to preempt statutes such as Maine Rx. Indeed, it appears likely that the federal government will be making fundamental changes in this area of public policy soon. On July 26, 2001, the Secretary of the Department of Health and Human Services testified that his agency is creating and promoting new Medicare Rx discount programs that are strikingly similar to the Maine Rx program. *Medicare Modernization: Examining the President's Framework for Strengthening the Program*, Subcomm. On Health of the House Comm. on Energy and Commerce, 107th Cong. (July 26, 2001) (Testimony of Tommy Thompson, Secretary, Dept. of Health and Human Services), http://energycommerce.house.gov/107/hearings/07262001Hearing339/Thompson549.htm at 6 (last visited August 22, 2001). According to Secretary Thompson, Medicare beneficiaries will no longer have to "pay the full cost of their medications out-of-pocket" because they "will have access to greater bargaining power," under the new federal programs. And, according to the Secretary, this program is being implemented even while "Congress debates Medicare reform and the creation of a prescription drug benefit." *Id.* Such imminent action by the federal government

to make prescription drugs more accessible to those least able to afford them may ultimately moot any national significance of Maine's foray into the field.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be denied.

Respectfully submitted,

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